

THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the application of Straub

Serial No.: 09/650,584

Filed: August 30, 2000

For: OPTHALMIC DEVICE AND
METHOD OF MANUFACTURE
AND USE

DKT: RES-101A

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TECHNOLOGY CENTER P3700

Assistant Commissioner for Patents
Washington, D.C. 20231

SUPPLEMENTAL INFORMATION DISCLOSURE

In compliance with the duty of disclosure under 37 C.F.R. §§1.56 it is respectfully requested that this Information Disclosure Statement be entered and the documents listed on the attached form PTO-1449 be considered by the Examiner and made of record. No Office Action on the merits has yet been received, and this Information Disclosure Statement is believed timely. If, however, an Office Action has been mailed and a fee is required, the Commissioner is hereby authorized to charge said fee (or credit any over payment) to Deposit Account 12-2147.

The enclosed French DEMANDE DE BREVET D'INVENTION to Baikoff Pub. No. 2,784,287 entitled "Segment D'Expansion Sclerale" is in the French language. An English language translation will be promptly provided.

USSN: 09/650,584

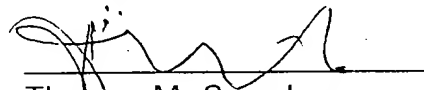
Page 2

In accordance with 37 C.F.R. § 1.56(a), this Disclosure Statement is not to be construed as a representation that a search has been made or that no other possibly material information as defined in 37 C.F.R. § 1.56(a) exists.

Applicant believes this application is in condition for allowance, which is respectfully requested.

April 4, 2001

Respectfully submitted,
LORUSSO & LOUD

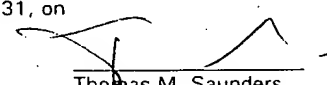


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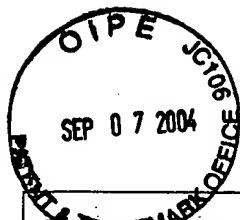
CERTIFICATE OF MAILING

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April 4, 2001



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Form PTO-1449 (Modified) List of Patents and Publications for Applicant's Information Disclosure Statement	Atty Docket No. RES-101A	Serial No. 09/650,584
	Applicant(s): Straub	
	Filing Date: August 30, 2000	Group:

Foreign Patent Documents

Exam. Init.	Doc. Number	Date	Country	Class/Subclass	Translation Yes/No
	2,784,287	10/13/98	FR		no

EXAMINER: _____
DATE CONSIDERED: _____

EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

The "Received" stamp of the Patent Office
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Supplemental Information Disclosure;
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Description of paper and No.

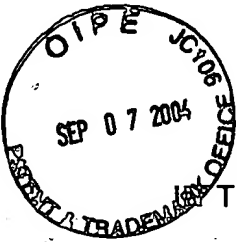
Name of applicant Straub

Intf. or Serial No. 09/650,588

Atty: TMS

Date: April 4, 2001





THE UNITED STATES PATENT AND TRADEMARK OFFICE

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ADDENDUM TO SUPPLEMENTAL INFORMATION DISCLOSURE

English Language Translation of Baikoff Pub. No. 2,784,287 "Segment D'Expansion Sclerale" & CERTIFICATION OF TRANSLATION

On April 4, 2001 the above-noted Applicant filed a Supplemental Information Disclosure. As of April 4, 2001 (and to date), no Office Action on the merits has been received. This Addendum to the timely Supplemental Information Disclosure provides a translation of a disclosed document. This Addendum to Supplemental Information Disclosure is believed to be timely filed.

The Supplemental Information Disclosure Statement of April 4, 2001 provided French DEMANDE DE BREVET D'INVENTION to Baikoff Pub. No. 2,784,287 entitled "Segment D'Expansion Sclerale" ("Baikoff"). Baikoff, as provided on April 4, 2001, was in the French language. The Supplemental Information Disclosure stated that an English language translation of Baikoff would be provided by the Applicant. Accordingly, an English language translation of

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Baikoff is enclosed herewith. Also enclosed is a CERTIFICATION OF TRANSLATION as signed by the translator, Ronald A. Masi.

Based on the timely filing of April 4, 2001, Applicant believes that no fee is required. If, however, a fee is required, the Commissioner is hereby authorized to charge said fee to Deposit Account 12-2147.

Applicant believes this application is in condition for allowance, which is respectfully requested.

May 21, 2001

Respectfully submitted,
LORUSSO & LOUD

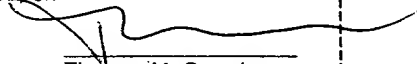


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May 21, 2001



Thomas M. Saunders



ADDENDUM TO SUPPLEMENTAL INFORMATION DISCLOSURE, with
Certificate of Mailing dated May 21, 2001 and fee

The "Received" stamp of the Patent Office
imprinted hereon acknowledges the filing of:

authorization; Translation into English of Fr. Brevet
Pub. No. 2,784,287 of 10 pages, and Certification of
Description of paper and No.

Translation
Name of applicant Straub

Intf. or Serial No. 09/650,584

Att'y: TMS

DKT: RES-101A

Date: May 21, 2001

CERTIFICATE OF TRANSLATION

1. Ronald A. Masi do hereby certify that:
(print translator's name)

1. I am well acquainted with the French and English languages.
2. That to the best of my knowledge and belief the following is a true translation by me of French patent application 2 784 287 to Baikoff filed October 13, 1998 (13.10.98).
3. I further declare that all statements made herein of my own knowledge and belief are believed true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Ronald A. Masi
By:

Date: 5-4-01

19. REPUBLIC OF FRANCE

NATIONAL INSTITUTE OF
INDUSTRIAL PROPERTY
PARIS

11. Publication no. 2,784,287
(to be used solely for copy orders)

21. National registration no.:
98 12834

51. Int. Class 7: A 61 F 2/14

12.

INVENTION PATENT APPLICATION

A1

22. Filing date: 10-13-98
30. Priority:

71. Applicant(s): Georges Baikoff, FR

72. Inventor(s): Georges Baikoff

43. Date application made available to the public: 4-14-00,
Bulletin 00/15.

56. List of documents cited in the preliminary search report: Refer
to the end of this document.

60. References to other related national documents:

73. Holder(s)

74. Agent(s): Cabinet [Law offices of] Loyer

54. SCLERAL EXPANSION SEGMENT

57. This invention concerns a scleral expansion segment consisting of an bendable arched bar intended to be placed on the sclera opposite the ciliary processes. The free ends of said bar are shaped like paddles that are wider than the diameter of said bridge (3) so as to form wide support feet (1, 2).

SCLERAL EXPANSION SEGMENT

This invention generally pertains to the correction of vision through the insertion of a corrective element into the eye, and more specifically the correction of presbyopia.

According to new theories, presbyopia is not only connected with a loss of the flexibility of the crystalline lens with age, but is allegedly primarily due to an increase in the diameter of said crystalline lens with age.

As shown in Figure 8, crystalline lens Cr enclosed in crystalline capsule S is suspended from sclera Sc along a ring of the sclera placed behind limbus corneae L separating vitreous body V from opaque body O. This suspension of the crystalline lens is provided by ligament Z, called the zonule, attached to ciliary processes Cc. Since the dimension of the scleral ring and ciliary processes Cc does not change over time, zonule Z is stretched little by little as crystalline lens Cr grows larger and loses a portion of its traction power on the equator of crystalline capsule S.

As a result, a new surgical method has been proposed to correct presbyopia in which the diameter of the scleral ring at the ciliary processes is increased so as to restretch the zonule so that it can once again serve its purpose of distorting the crystalline lens through the effect of the ciliary muscle's contraction and restore the eye's accommodating power.

Schachar proposed a truncated ring implanted by suturing around the scleral ring (US patent no. 5,465,737).

This ring, however, requires a very long and delicate surgical procedure and involves painful post-operative sequela for the patient.

As a consequence, a more recent proposal was made for arched segments that are installed in belt loops incised in the thickness of the sclera concentrically with the limbus at the ciliary processes, with these segments acting as stiffeners exerting an outward traction, thereby restretching the zonule. In practice,

four scleral segments at 90° to each other are used.

This intervention yields much better results than the installation of the complete ring initially proposed by Schachar because the surgery is simple and quick (incision of four tunnels serving as the belt loops and insertion of the segments) and eliminates all other sutures, and therefore considerably reduces the discomfort of the patient and the post-operative consequences. This technique is illustrated schematically in Figure 9.

In this figure we can see a fragment of sclera Sc in which tunnel T acting as a belt loop has been made.

Segment Sg has been inserted into this loop and rests, by means of feet A and B, on the sclera on which it exerts pressure, whereas bridge C exerts an outward traction force. We can see that the zonule is stretched at Z1 in line with force C and relaxed at Z2 in line with forces A and B.

However, the current segments, which are simple cylindrical bendable bars, present a substantial risk of perforating the sclera on account of the fact that they press against the sclera on small surfaces.

The purpose of this invention is to eliminate this drawback and propose scleral expansion segments that do not present any risk of perforating the sclera.

According to the invention, the scleral expansion segment, which, by a known means, consists of an arched bendable bar intended to be placed on the sclera at the ciliary processes, is characterized by the fact that its free ends have a paddle-like shape that is broader than the diameter of said bar so as to form large support feet.

The segment according to the invention is furthermore worthy of note in that:

- the feet have a radius of curvature R1 corresponding to that of the sclera at the ciliary processes, whereas the bridge has a radius of curvature R2 that is less than R1;
- it has a multitude of perforations;
- it is covered with synthetic biocompatible material having

a porous surface;

- it is made with a core made of distortable material retaining its original shape, embedded in a layer of soft material;
- it has an internal channel intended for the installation of a core whose type and strength can be chosen in order to adjust the effect of the scleral expansion segment;
- the core consists of an injectable product;
- it is made of two parts that snap together;
- the first part consists of a foot equipped with a female attachment part, whereas the second part consists of the other foot together with the bridge whose free end has a male attachment part;
- both parts have devices for preventing any relative rotation of one part with respect to the other.

The invention will be better understood thanks to the description that will now follow, given as a non-limiting example in reference to the attached drawings in which:

- Figure 1 is a top view of a scleral expansion segment according to the first embodiment of the invention;
- Figure 2 is a side view of the scleral expansion segment of Figure 1;
- Figure 3 is a top view of a scleral expansion segment according to the second embodiment of the invention;
- Figures 4a and 4b are cross-sectional views along lines A-A and B-B of Figure 1, respectively;
- Figure 5 is a top view of a scleral expansion segment according to the third embodiment of the invention;
- Figure 6 shows the scleral expansion segment of Figure 5 after assembly;
- Figures 7a to 7c are schematic representations of placements in the eye of the scleral expansion segments of the invention;
- Figure 8 is a schematic cross section of an eye;
- Figure 9 is a partial schematic cross-sectional view of an eye provided with a scleral expansion segment.

As shown in Figure 1, the scleral expansion segment of the invention consists of an arched bendable bar having two ends

forming two feet, items 1 and 2, connected together by cylindrical bridge 3. Feet 1 and 2 consist of paddle-shaped parts that are wider than the diameter of bridge 3 and their inward surfaces are flattened. This arrangement allows the scleral expansion segment to rest on the sclera over a relatively extensive surface, thereby considerably reducing the pressure directed inward toward the eye that is exerted on the surface of the sclera.

As can be seen in Figure 2, the scleral expansion segment is an arched piece having two radii of curvature. Feet 1 and 2 have a radius of curvature $R1$ corresponding to that of the sclera Sc at the ciliary processes, whereas bridge 3 has a radius of curvature $R2$ that is less than $R1$ so as to pull against the scleral loop.

In the embodiment examples shown in the drawings, the feet, as seen from above, have a generally ellipsoidal shape. Their ends are rounded to prevent any injury to the sclera.

The material used to make the scleral expansion segment is a synthetic biocompatible material such as PMMA, polyhema, or ceramic material.

In the embodiment variant shown in Figure 3, the scleral expansion segment has a multitude of perforations, item 4, through which the connective tissue can develop in order to improve the bond between the sclera and said correction segment and/or to serve as a passage point for a possible suture, if necessary.

According to an embodiment not shown in the drawings, the creation of holes 4 can be replaced by providing the scleral expansion segment with a porous surface having a sufficiently large mesh to accommodate colonization by the connective tissue. Such a surface is made, for example, by covering the segment with a synthetic biocompatible material, a hydroxyapatite, a component with variable hydration, etc.

The scleral expansion segment of this invention may also be designed in such a way that its action is adjustable, that is, so that its shape can be modified in order to adjust its effect on the zonule at the time of implantation or if it were to decrease over time.

To this end, and as shown in Figures 4a and 4b illustrating a cross sectional view of bridge 3 and a cross sectional view of a foot, item 1 or 2, respectively, the scleral expansion segment has core 5 and 50 made of a stiff material capable of retaining the shape that it has been given, embedded in a soft material, items 6 and 60.

The material forming core 5 is preferably chosen from among the shape-retaining distortable materials.

According to an embodiment not shown in the drawings, the scleral expansion segment has an inner channel intended for the installation of a core whose type and strength can be chosen by the practitioner in order to adjust the effect of the scleral expansion segment to the condition of the eye being treated.

Since bridge 3 of the scleral expansion segment can have a diameter of roughly 0.6 millimeter, the inner channel intended to contain the core can have a diameter of about 0.2 millimeter.

Such a removable core can be made in the form of a solid body that is inserted into the scleral expansion segment.

It can also consist of an injectable product that is placed in the channel formed in the scleral expansion segment, with the effect of the scleral expansion segment being adjusted by modulating the pressure of the product introduced into said segment.

The product injected into the channel of the scleral expansion segment may be a polymerizable or non-polymerizable gas, liquid, or gel.

Owing to the fact that the scleral expansion segment of the invention has feet that are larger than the bridge passing through the belt loop incised in the sclera, it is apparent that the surgeon must either make a wider incision or force the foot of the segment through the loop. In the first case, the surgeon runs the risk of having the segment improperly held in place and inadequate traction of the segment on the zonule. In the second case, there is a risk of injury to the sclera.

For this reason, using a particularly beneficial embodiment,

the invention calls for the scleral expansion segment to be made in two parts that snap together and are arranged such that one of the ends of the bridge is free for insertion of the segment through the belt loop.

Such a segment is shown in Figures 5 and 6.

It consists of two parts, 7 and 8, that can be fastened to each other by means of fastening devices 9 and 10.

As shown in Figure 5, the first part, item 7, has a foot, foot 1 in the embodiment shown in the drawing, whereas the second part, item 8, has the second foot, item 2, and bridge 3.

The end of bridge 3 is shaped to form a fastening device, item 9, made to work with a complementary fastening device, item 10, that is part of the first part, 7.

In the embodiment shown in the drawing, bridge 3 of part 8 has male fastening device 9 roughly shaped like a harpoon, and part 7 has female fastening device 10 consisting of a cavity having a complementary shape to harpoon 9.

In order to avoid any risk of trauma, rounded ends will preferably be used for fastening devices 9 and 10.

In order to avoid any installation error between the two parts or any inadvertent rotation of one part with respect to the other after installation, grooves are also preferably made on the perimeter of the free end of the bridge (for example, 3 grooves at 120°) engaging with corresponding grooves on the inner perimeter of cavity 10 for engaging the segment's foot.

The beginning of this description indicated that the segments are generally used in groups of 4 placed roughly at 90° angles opposite the ciliary processes, about 3 mm behind the limbus (Figure 6c), but one can adopt other arrangements such as two segments in polar positions (Figure 6a) or three segments spaced 120° apart (Figure 6b).

For instance, the scleral expansion segments have a length of about 3 to 5 millimeters, with their feet having, for example, a width of between 1 and 2 millimeters.

In addition to the safety and ease of installation they

provide, the scleral expansion segments of this invention have the benefit of being placed and modified very easily in the course of the operation to adapt the curvature of their bridge to the desired outward traction.

The above description gave embodiment examples in which the scleral expansion segment has a bridge in the shape of a cylindrical bar, but the bridge could have any other shape (blade, band, etc.) without exceeding the scope of this invention, provided that the bridge connects wider feet.

Lastly, if a surgical procedure should be necessary on an eye containing the segments of this invention, said segments can easily be removed either by disassembling them or by cutting them near one of the pressure feet.

CLAIMS

1. A scleral expansion segment consisting of an arched bendable bar intended to be placed on the sclera opposite the ciliary processes, wherein the free ends of said bar have a paddle-like shape that is wider than the diameter of said bridge (3) so as to form wide support feet (1, 2).

2. A segment according to claim 1 wherein the feet (1, 2) have a radius of curvature R1 corresponding to that of the sclera opposite the ciliary processes, whereas the bridge (3) has a radius of curvature R2 less than R1.

3. A segment according to claim 2 characterized by the fact that it has a multitude of perforations (4).

4. A segment according to claim 2 characterized by the fact that it is covered with a synthetic biocompatible material having a porous surface.

5. A segment according to any one of claims 1 through 4 characterized by the fact that it consists of a core (5, 50) made of a distortable material that retains its shape, embedded in a layer of soft material (6, 60).

6. A segment according to any one of claims 1 through 4 characterized by the fact that it has an inner channel intended for the insertion of a core whose type and strength can be chosen in order to adjust the effect of the scleral expansion segment.

7. A segment according to claim 6 wherein the core consists of an injectable product.

8. A segment according to any one of claims 1 through 7 characterized by the fact that it is made of two parts (7, 8) that snap together.

9. A segment according to claim 8 wherein the first part (7) consists of a foot (1) having a female attachment device (10), whereas the second part (8) consists of the other foot (2) together with the bridge (3) whose free end has a male attachment device (9).

10. A segment according to claim 8 or claim 9 wherein the two

parts (7, 8) have devices to prevent any relative rotation of one with respect to the other.